IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit	: 3731	
Examiner	: Gwen G. Phanijphand	
Serial No.	: 09/917,385	
Filed	: 7/27/01	
Inventor	: Lisa A.G. Tweardy	Docket No.: 1461-R-00
	:	
Title	: CERAMIC-TIPPED	Confirmation No.: 9974
	: SKULL PINS	Dated: July 14, 2003

DECLARATION OF LISA A. G. TWEARDY

Lisa A. G. Tweardy makes the following declaration:

1. I am a research scientist employed by The Jerome Group, Inc.
2. I have worked in the field of biomedical engineering since 1986.
3. My educational background is as follows:

   B.S. Fundamental Sciences (Biomedical Engineering), Lehigh University, 1986.
   M.S.E. Management of Technology, University of Pennsylvania, 1995.

4. There is an unmet need for providing skull pin tip that inhibits patient burning during imaging procedures such as MRI, yet maintains the strength and functionality necessary for medical traction applications. Patient complaints were observed at least as long as ten years ago.
5. The invention described in the patent application having serial number 09/917,385 ("the Invention") addresses the problem of skull pin strength and patient burning by providing a pin tip made of an insulating material and having a shape that provides sufficient strength while allowing penetration into bone. It has been found that a rounded pin tip having a radius in the range of about 0.025 - 0.075 mm provides the necessary strength and allows penetration into bone.
6. Mechanical tests were performed which simulated maximum mechanical loading in normal clinical use. These results demonstrated that the pin tips according to the claimed Invention exceed the ultimate strength of human skull bone and meet or exceed the ultimate loading performance of titanium alloy halo and/or tong pins. The pins withstand a minimum axial load of 200 lbs. per pin at 8 inch.pounds of torque.
7. Electrical testing was performed using apparatus and fixturing intended to determine the complex impedance as an intrinsic material property. The primary conclusion was that the pins as fabricated (according to the Invention as claimed) provides high values of complex impedance relative to metallic pins across a wide range of frequencies. This means that the pins are effective barriers to the passage of electromagnetic energy under the operating conditions of the MRI.
8. Neither Rieser nor Bremer (6,387,129, 4,612,930 and 5,042,462) teach using a pin tip of the geometry claimed in application no. 09/917,385 to provide sufficient strength and functionality to the pin tip.

8. The Invention goes beyond merely combining Bremer and Rieser by recognizing the significance of pin ship shape.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with knowledge that willful false statements so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful and false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 07/17/03

Lisa Twardy